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UNITED NATIONS DEVELOPMENT PROGRAMME

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ENGLISH

APPROVAL OF UNDP ASSISTANCE TO A PROJECT OF
CUBA

IPF:(1992-96) $10 903 000

(CUB/91/010) - Production of Monoclonal Antibodies

Date of approval by the AC:[1/]	18 December 1991
Expected duration:	Three years
Proposed executing agency:	Government
Government implementing agency:	Center for Molecular Immunology
Proposed UNDP contribution:	$ 800 000 Source of funds: IPF
Total UNDP budget:	$ 800 000

Project background

The development of Cuba's biotechnological industry is currently among the Government's principal national development objectives. As outlined in the Fifth Country Programme (1992-1996), fostering the growth of this subsector has two main objectives: first, to acquire the medicaments to fight the country's leading malign diseases which are the latest challenge in public health; and second, to diversify the country's economy, establish leading sectors around the production of non-traditional exports, and the need to make the country less dependent on imports.

In the last thirty years, Cuba has achieved vast improvements in the field of public health. An infant mortality rate of 11.1/1000 and life expectancy of 73 and 76 years among men and women respectively, are among the best in the hemisphere. These advances have encouraged the Government to allocate resources for the development of technologies which will fight more complex diseases such as cancer, immune deficiencies, AIDS, rejection of transplants, etc.. On the other hand, Cuba is facing a serious challenge in its economic sphere. The economy is heavily dependent on external trade, especially on sugar, the commodity price of which is presently depressed in world markets. A biotechnological industry would help fulfil the need to diversify the country's exports with products which carry a high value added content.

During the course of the last ten years, Cuba has invested and accumulated valuable resources and experience in the field of biotechnology. Biotechnology was initially developed by national research institutions in 1981 and flourished since then, on account of the country's specialized human resources and abundant scientific facilities. In this field, the production of monoclonal antibodies has been emphasized. Monoclonal antibodies

[1/] **This Fact Sheet reflects the status of the project/revision at the time it was approved by the Action Committee; modifications to the project/revision may have occurred subsequently.**

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are proteins belonging to the body's defense mechanism which have proven effective in diagnosing and treating several complex diseases. Their most marked characteristic involves their ability to track and destroy antigens without harming healthy body parts.

To scale up the production of monoclonal antibodies, and select the best technology for cultivating superior cells, and specialized equipment used for the production process, the Government requested UNDP assistance under the present approval.

Description of project

The development objective of the project is to supply monoclonal antibodies which will be used to diagnose and treat various diseases.

The immediate objectives of the project are to : (a) enable the Center for Molecular Immunology of the Ministry of Public Health to provide most of the equipment for the production plant; (b) bring the production capacity of the plant to industrial scale and enable it to reach approximate 1 Kg/yr by the end of the project; and (c) satisfy the national necessity with a production capacity of 5 kg/yr which will be used for export production following the end of the project.

Project activities will include : (a) transferring the technology needed for the up-scaled production; (b) equipping the production plant (i.e. bioreactors, fermenters, etc.); (c) training 120 technicians and scientists in specialized areas (i.e. operation of bioreactors and fermentators, and generation of chimeric and reformed monoclonal antibodies); and (d) elaborating a quality control system, a technical document of the production system, and its patent registration.

Inputs

UNDP will provide seven work-months of short-term international experts to start up operations in cellular cultures production, heterogeneous systems development, and quality control; 40 work-months of training in the areas of bioreactor and fermenters operations, chromatography at a pilot scale, chimeric antibodies, and murine viruses; visits to other production plants; equipment for the cultivation of suspension cells, and for the laboratories to be used in quality control; and subcontracts to verify the quality of the product.

Financial data

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Personnel	89 000
Subcontract	90 000
Training	265 000
Equipment	353 000
Miscellaneous	3 000
Total	800 000

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